K063095

NEWCLIP

DEC 2 2 2006

4. 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter's Name and adress

NEWCLIP TECHNICS
Z.A du Pâtis
Rue de la fontaine grillée
F-44 690 La Haye-Fouassiere
France
Tele : (33) 2 28 21 37 12
Fax : (33) 2 40 63 68 37

Summary preparation date: October 6, 2006

B. Official Contact Person

J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
Tele/Fax – 512-388-0199
Email - ortho.medix@sbcglobal.net

C. Establishment registration number : Applied for

D. Device name

Humerus Locking Plating System

E. Device Classification Name

Plate, fixation, bone (21 CFR 888.3030)
Screw, fixation, bone (21 CFR 888.3040)

F. Proposed regulatory Class

Class II

G. Device Product Code

HRS
HWC

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H. Panel Code

Orthopedic

I. Device Description

The Humerus Locking Plating System consists of plates designed for various fracture modes of the humerus bone. The system is used with locking screws, smooth locking pegs, threaded locking peg, locking cortical screws and standard cortical screws. The locking screws, threaded pegs and pegs could be supplied cannulated or not. Each device is manufactured from titanium alloy Ti-6Al-V4 ELI (conforms to ASTM F 136-02a and/or ISO 5832-3) or stainless steel (conforms to ASTM F 138 and/or ISO 5832-1). Each device can be supplied color anodized or non-anodized.

The Humerus Locking Plating System will be provided non-sterile for steam sterilization by health care professionals prior to use.

J. Intended use:

The Humerus Locking Plating System is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal Humerus.

K. Predicate device:

- Modified Shoulder Fixation System of HAND INNOVATIONS (K051728)
- SYNTHES LCP® Proximal Humerus Plates, long of SYNTHES (K041860)
- Proximal Humerus Plate of ACUMED (K012655)
- Stryker Plating System of HOWMEDICA OSTEONICS CORP. (K060798)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Newclip Technics
% Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

DEC 22 2006

Re: K063095
Trade/Device Name: Humerus Locking Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 29, 2006
Received: October 13, 2006

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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3. INDICATIONS FOR USE

510(k) Number (if known): K063095

Device Name: Humerus Locking Plating System

Indications for Use:

The Humerus Locking Plating System is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Prescription Use X
AND/OR
Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063095